

## Reference Material

This certificate is designed in accordance with ISO 17034 and ISO Guide 31. This reference material (RM) was designed, produced and verified in accordance with ISO/IEC 17025, ISO 17034 and a registered quality management system ISO 9001.

### Product Name

Cefalexin monohydrate

### Product Code

DRE-C11064000

### CAS No.

23325-78-2

### Mol. Weight

365.40

### Mol. Formula

$C_{16}H_{17}N_3O_4S \cdot H_2O$

### Lot Number

G1408939

### Format

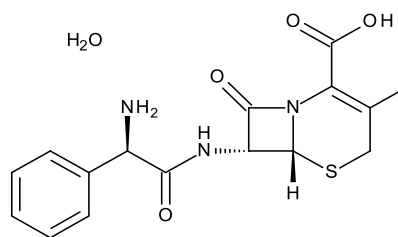
Neat

### Expiry Date

11 Dec 2027

### Storage Temp

20°C ± 4°C



**CERTIFIED**

Purity  
98.27% (g/g)

**CERTIFIED**

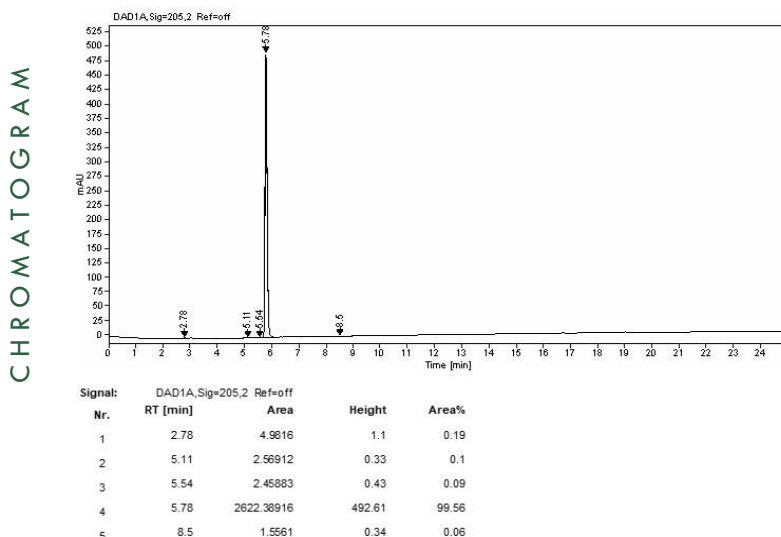
Expanded Uncertainty (U)  
0.57% (g/g)

### Uncertainty

The certified value(s) and uncertainty(ies) are determined in accordance with ISO 17034 with an 95% confidence level ( $k=2$ ). Uncertainty is based on the Total Combined Uncertainty, including uncertainties of characterisation, homogeneity and stability testing. Stability values are based on real evidence opposed to simulation.

The producer certifies that this reference material meets the specification stated in this certificate until the expiry date, provided it is stored unopened at the recommended temperature herein. Product warranties for this reference material are set out in the terms and conditions of purchase.

CERTIFIED BY	CERTIFIED ON		RM Release
L. Messerschmid	11 Dec 2023		

**Instrument**

HPLC/DAD

**Detection**

DAD

**Column**

Nucleodur 100 C8, 3 µm, 250 x 4 mm

**Method Details**

see Batch Information

**Inj.-Vol.**

10.0 µL

**Flow**

1 mL/min

**Method of Characterisation**

Purity = 100% - Assay impurities – Water excess (KF) – Residual Solvents (NMR)

**Method of Identification**

EA, NMR, RT, IR, MS, UV

**Batch Information**

Water Content: 6.07% (g/g) by Karl-Fischer-Titration (U(exp) = 0.26% (g/g)).

**Method Details**

Eluent A: 100% Acetonitrile

Eluent B: Water + H3PO4

Time [min]	Eluent A [%]	Eluent B [%]
0	10	90
1	10	90
20	98	2
25	98	2

**Intended Use**

This RM is intended for use in a laboratory as a calibration and quality control standard or in method development for analytical techniques.

**Safety**

Proper precautions should be observed while handling. See Safety Data Sheet.

**Traceability**

The balances used for gravimetric measurements are calibrated with weights traceable to the national standards (DKD). The calibration of

the balances is verified daily internally and annually by an external accredited calibration service. Chromatographic methods are traceable to the International System of Units (SI).

**Homogeneity**

Random replicate samples of the final packaged RM have been analysed to prove homogeneity compliant with ISO 17034.

**Storage**

The RM should be stored in the original sealed container at the indicated temperature.

**Instructions for use**

It is recommended to use 1 mg as the minimum sample size and if less material is used, to increase the certified uncertainty by a factor of two for half sample and four for a quarter of sample. If storage after opening is necessary, the RM should be tightly closed and kept from light and moisture. If the RM was in a sealed ampoule, it should be transferred to a vial with minimum head space. Visit the support section of our website [lgcstandards.com](http://lgcstandards.com) for a series of Dr. Ehrenstorfer Tech Tip videos and frequently asked questions.

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LGC Labor GmbH is accredited by DAkkS as reference material producer on ISO 17034 (D-RM-19883-01-00).

All characterisation measurements at LGC Labor GmbH are accredited methods to ISO/IEC 17025.

